

Sec. 6: 510(k) Summary – Global Medi Products Retractable Safety Syringe



OCT 17 2012

Date Summary was Prepared	October 17, 2012 rev1.
510(k) Submitter	Mr. Graeme Walton, President Global Medi products. Bundall BC PO Box 6526 Gold Coast MC QLD 9726 Australia (p) +61-400-156 777 Email: graemewalton@globalmp.com.au
Primary Contact for this 510(k) Submission	Mr. Graeme Walton, President Global Medi products. Bundall BC PO Box 6526 Gold Coast MC QLD 9726 Australia (p) +61-400-156 777 Email: graemewalton@globalmp.com.au
Device Common Name	Syringe, Antistick
Trade Name	Global Medi Products Retractable Safety Syringe
Device Product Codes and Classification Name	MEG, 21CFR880.5860, Piston Syringe FMI, 21CFR880.5570, Needle, Hypodermic, Single Lumen
Predicate Device	M.K. MEDITECH CO. LTD, DUOPRO SAFETY SYRINGE (DUOPROSS) K022806
Device Description	<p>The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male luer lock connector (nozzle) for fitting the female luer connector (hub) of a hypodermic single lumen needle. Note: the 1ml Retractable Safety Syringe has an integral 25Gx1" hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body. The function of the Global Medi Products Retractable Safety Syringe works the same as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after patient injection. Needle retraction is activated by the syringe user. Because the needle is manually withdrawn into the syringe barrel, the syringe user is protected from accidental needle sticks. These accidental needle sticks could occur between removing the needle from the patient and disposing of the syringe in a sharps disposal container.</p> <p>The Global Medi Products Retractable Safety Syringe is packaged, sterilized and delivered in a ready to use condition. It is not compatible with, and is not intended to be used with any other needles or syringe accessories.</p> <p>The syringe barrel, plunger, needle base, needle cap, needle base cap are manufactured from medical grade polypropylene and tested for biocompatibility. The piston, seal and o-ring are manufactured from medical grade rubber and also tested for biocompatibility. The needle assemblies are manufactured from AISI 304 stainless steel and documented as biocompatible.</p> <p>The operating principles and method for the Global Medi Products Retractable Safety Syringe is substantially equivalent to the predicate device. The needle is retracted manually and enclosed within the syringe barrel one the injection has been completed. Once the plunger is fully retracted and 'snapped' off the device is rendered non-reusable. Differences between the Global Medi Products Retractable Safety Syringe and the predicate device are (1) Global Medi Products are sterilized via validated ETO gas sterilization process to a 10^{-6} SAL, as is the predicate device, (2) there are minor dimensional differences, these dimensional differences do not affect performance or raise new issues of safety and effectiveness.</p>

Intended Use	Indications for Use: The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable manual retractable safety syringe intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse.
Technological Characteristics	Global Medi Products makes the claim of substantial equivalence of the GMP Retractable Safety Syringe to the Meditech Co. DuoProSS Retractable Safety Syringe based on similarities in intended use, design, technological, and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce risks of sharps injuries. The GMP Retractable Safety Syringe are always provided with preassembled needles whereas the DuoProSS can be ordered with and without needles. GMP Retractable Safety Syringe currently uses a male luer lock needle connector design where the DuoProSS uses a luer slip ne connector design. Both syringes are provided sterile, single use, and disposable. There are minor differences between the GMP Retractable Safety Syringe and DuoProSS which is syringe volume (and associated dimensions). This difference does not affect the performance of the syringe, since syringe size is typically determined by drug volume to be administered and user preferences. Both syringes have two part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. Both syringes require the user to manually retract the needle-plunger into the syringe barrel, break of the plunger rod, and discard the pieces. Global Medi Products believes that the differences between the GMP Retractable Safety Syringe and the predicate device are minor and they raise no new issues of safety or effectiveness.
Summary of Testing	Global Medi Products Retractable Safety Syringe is substantially equivalent and meets the same acceptance criteria as the predicate device in K022806. Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization, systemic toxicity, interactions with blood) in compliance with the methods of ISO 10993-4, -5, -10, -11, Syringe performance per ISO 7886-1 Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use, ; ISO7886-4; Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature, ISO 594, Conical fittings with a 6 % (Luer) taper for syringes ;ISO 11135; Sterilization Validation ETO, GB/T14233.1 (GB / T 14233.1- 1998 Infusion, transfusion, injection equipment for test methods - Part 1 Methods for chemical analysis. (EO Residuals), ISO 10993-7, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals. ISO 10993-7:2008 specifies allowable limits for residual ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH. Hypodermic needles have been tested in accordance with ISO 7864: 1993; Sterile hypodermic needles for single use and ISO 594-1:1986 ISO594-2:1998 Conical fittings with a 6 % (Luer) taper.
Substantial Equivalence	The Retractable Safety Syringe described in this 510(k) submission is substantially equivalent in all specifications and performance compared to the predicate device indentified in K022806



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Global Medi Products
C/O Robert O. Dean
President
Compliance Systems International, Limited Liability Company
1083 Delaware Avenue
Buffalo, New York 14209

OCT 17 2012

Re: K120641
Trade/Device Name: Global Medi Products Retractable Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: October 10, 2012
Received: October 16, 2012

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

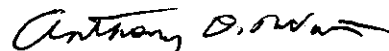
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Form

Indications for Use:

510(k) Number (if known): K120641

Device Name: Global Medi Products Retractable Safety Syringe

Indications for Use: The Global Medi Products Retractable Safety Syringe is a sterile, single use, disposable and non-reusable manual retractable safety syringe intended for medical purposes for injection of fluids into the body, while reducing the risks of sharps injuries and the potential for syringe reuse.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

 10/18/12

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120641